# News Release

## Cardiovascular Systems Enrolls First Patient in Coast Study

- **International Coronary Trial Taking Place in United States and Japan**
- **Study to Assess Safety and Efficacy of New Coronary Micro Crown**

ST. PAUL, Minn.--(BUSINESS WIRE)--Jun. 11, 2014-- Cardiovascular Systems, Inc. (CSI) (NASDAQ:CSII), announced that the first patient has been enrolled in its Coronary Orbital Atherectomy System Trial (COAST) trial. Taking place in the United States and Japan, the study is designed to assess the safety and efficacy, as well as economic outcomes, of CSI's new micro crown Orbital Atherectomy System (OAS) in treating severely calcified coronary lesions in patients suffering from Coronary Artery Disease (CAD). Dr. Arthur Lee, North Florida Regional Medical Center, Gainesville, Fla., performed the first procedure.

The micro crown is CSI's second-generation system designed to facilitate stent delivery in subjects with CAD who are acceptable candidates for p*ercutaneous transluminal coronary angioplasty (*PTCA) or stenting. The micro crown OAS is designed to improve the tracking and piloting of the OAS driveshaft and the ability of the crown to reach the lesion while operating at low rotational speeds.

"During my first procedure using CSI's new micro crown OAS, I modified a calcified lesion allowing stent delivery and expansion," said Dr. Lee. "I'm encouraged by CSI's commitment to advancing and improving the technology by expeditiously releasing a second generation of technology in a space that has been stagnant for 25 years."

Building on CSI's ORBIT II study, the first study designed to enroll severely calcified lesions that are typically excluded from all major trials but commonly seen in the real world cases, COAST is a prospective, single-arm, multi-center, global, investigational study designed to evaluate the safety and efficacy of CSI's new micro crown OAS in these difficult to treat lesions.

Up to 100 subjects may be enrolled at up to 15 U.S. sites and five sites in Japan. Minimum enrollment is 50 patients in the United States and 25 in Japan. Dr. Gregg Stone, Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, and Dr. Shigeru Saito, Director of Cardiology and Catheterization Laboratories, Shonan Kamakura General Hospital, Kamakura, Japan, are the study's principal co-investigators.

Dr. Stone said: "We're excited for the potential of CSI's new micro crown OAS device to provide additional treatment options for heavily calcified lesions seen in the ORBIT II study."

"We're eager to launch our first international coronary study which will support the approval of our next-generation system in the United States and Japan," said David L. Martin, CSI president and chief executive officer. "COAST aligns with our ORBIT II data protocol and study details—giving CSI a further opportunity to build on the compelling results we delivered in ORBIT II. Additionally, it will highlight the potential benefits of our new micro crown and, we hope help secure commercial approval in Japan."

**About Coronary Artery Disease (CAD)**

CAD is a life-threatening condition and leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. According to the American Heart Association, 16.3 million

people in the United States have been diagnosed with CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives in the United States each year. According to estimates, significant arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention (PCI). Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (MACE).

**About Cardiovascular Systems, Inc.**

Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company's Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback Orbital Atherectomy System for the treatment of PAD in August 2007. In October 2013, the company received FDA approval for the use of the Diamondback Orbital Atherectomy System in coronary arteries. To date, over 146,000 of CSI's devices have been sold to leading institutions across the United States. For more information, visit the company's website at www.csi360.com (http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.csi360.com&esheet=50884102&newsitemid=20140611005430&lan=en-US&anchor=www.csi360.com&index=1&md5=5e907d29d8d12496be14205fda365fd5).

**Safe Harbor**

Certain statements in this news release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements in this press release regarding (i) the COAST trial; (ii) international expansion; and (iii) approval in Japan, are forward-looking statements. These statements involve risks and uncertainties which could cause results to differ materially from those projected, including but not limited to dependence on market growth; the reluctance of physicians and hospitals to accept new products; the effectiveness of the Stealth 360 and the Diamondback 360 Coronary OAS; actual clinical trial and study results; the impact of competitive products and pricing; the difficulty to successfully manage operating costs; fluctuations in quarterly results; government clearances and approvals; approval of products for reimbursement and the level of reimbursement; general economic conditions and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. CSI encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this release. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, CSI's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this release. The forward-looking statements made in this release are made only as of the date of this release, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.

**Micro Crown OAS**

CSI has commenced its COAST Investigational Device Exemption clinical trial to evaluate the safety and effectiveness of its new micro crown orbital technology in treating coronary arteries. **This new system is limited by federal law to investigational use and is currently not commercially available in the United States or Japan.**

Source: Cardiovascular Systems, Inc.

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